



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,452	06/14/2006	Andreas Lendlein	80062-2	3000
22504	7590	08/23/2007		
DAVIS WRIGHT TREMAINE, LLP			EXAMINER	
1201 Third Avenue, Suite 2200			GETTMAN, CHRISTINA DANIELLE	
SEATTLE, WA 98101-3045			ART UNIT	PAPER NUMBER
			3734	
			MAIL DATE	DELIVERY MODE
			08/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,452	Applicant(s) LENDLEIN ET AL.	
	Examiner Christina D. Gettman	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/14/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 13 is objected to because of the following informalities: the Examiner believes that claim 13 should be dependent from claim 12, not claim 11. If this is not the case, please state so in the response to this office action. Otherwise, appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Seward et al. (U.S. Patent No. 2002/0142119). Seward et al. disclose the invention as claimed including a stent made out of an SMP material (par. 77), the material having a two-shape memory (par. 76), the material being made from a polymer network (par. 54), the SMP effect induced thermally (par. 46-50), and the SMP material being biocompatible.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3734

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seward et al. as applied to claim 1. Seward et al. disclose the invention substantially as claimed including a method (par. 46-50, 76) of implanting a stent including placing a stent on a balloon catheter, inserting the stent to a desired position, heating the stent, expanding the stent, and inserting a cooling medium. Seward et al. also disclose a method (par. 77) of removing a stent including the steps of inserting a balloon catheter to the implantation location, inserting a heat medium, activating the SMP material of the stent, and removing the catheter along with the stent. Seward et al. disclose the invention substantially as claimed except for the stent having x-ray contrast substances or medically effective compounds or placing the stent onto a temperature-controlled balloon. X-ray contrast substances and medically effective compounds are well-known in the art to be used with stents. Therefore, it would have been obvious to have modified the stent of Seward et al. with either an x-ray contrast substance in order for the stent to be viewed in an x-ray or with a medically effective compound in order to promote the desired effects in, such as, a blood vessel. Placing a stent on and using a temperature-controlled balloon catheter is well-known in the art and would, therefore, be obvious to modify the method of implantation by using a temperature-controlled balloon catheter in order to insert the stent into, such as, the vasculature system.

Claims 6-9 rejected under 35 U.S.C. 103(a) as being unpatentable over Seward et al. as applied to claims 1 and 5 above, and further in view of Langer et al. (U.S.

Art Unit: 3734

Patent No. 6,388,043). Seward et al. disclose the invention substantially as claimed except for the SMP material having an e-module of 0.5 to 50 Mpa (col. 6, lines 66-67), the polymer network comprising caprolactone units (col. 8, lines 11-19), such as cross-linked caprolactonmacromonomers, or a method (col. 12, lines 63-64) of manufacturing the stent from a biodegradable SMP material using extrusion. Langer et al. teach the SMP material having an e-module of 0.5 to 50 Mpa for the purpose of strength, the polymer network comprising caprolactone units, such as cross-linked caprolactonmacromonomers, and a method of manufacturing the stent from a biodegradable SMP material using extrusion. Therefore, it would have been obvious to have modified Seward et al. with the SMP material having an e-module of 0.5 to 50 Mpa in order to provide the necessary strength to the vasculature and to prevent the stent from collapsing upon forces, the polymer network comprising caprolactone units, such as cross-linked caprolactonmacromonomers, and a method of manufacturing the stent from a biodegradable SMP material using extrusion.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina D. Gettman whose telephone number is 571-272-3128. The examiner can normally be reached on Monday-Friday 7:15 am to 3:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3734

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CG


Christina Gettman
Art Unit 3734
571-272-3128



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER